

COLDAEWON COUGH A- acetaminophen, ephedrine hcl, guaifenesin syrup
Daewon Pharmaceutical Co., Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ACTIVE INGREDIENT

Active ingredients (in each 20 mL pouch)

Acetaminophen 300 mg
Ephedrine HCl 18 mg
Guaifenesin 42 mg

INACTIVE INGREDIENT

Inactive ingredients:

xanthan gum, stevia 100s, acesulfame potassium, concentrated glycerin, sucralose, d-sorbitol solution, xylitol, sodium chloride, povidone K30, propylene glycol, ethanol, disodium edetate hydrate, citric acid, sodium citrate hydrate, sodium benzoate, lemon essence, apple mint flavor 514165, red no. 40, purified water

PURPOSE

Purpose:

- Pain reliever/fever reducer
- Nasal decongestant
- Expectorant

WARNINGS

Warnings:

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 8 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy Alert: If you have ever experienced allergic reactions induced by drugs. Symptoms may include: • Skin reddening • Blisters • Rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Reye's syndrome: a chickenpox or influenza-suspected infant or child under 15 years of age

If it is accompanied by nausea or vomit, it may be early symptoms of Reye's syndrome, rare but serious, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure

whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease • heart disease • renal disease • high blood pressure • thyroid disease • diabetes • glaucoma • dysuria • weak condition • high fever
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, pulmonary emphysema, and excessive sputum production
- trouble urinating due to enlarged prostate gland
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizer
- taking blood thinning drug warfarin

When using this product

- observe usage and dosage instructions.
- do not take this drug for a long term.
- children should take this drug under the guardians' supervision.
- do not drink alcohol while you are taking this drug.
- tends to cause drowsiness, avoid driving cars and operating machinery while taking this drug.
- patients, administered with barbitol drugs, tricyclic antidepressants, or alcohol, tend to lack the ability to metabolize lots of acetaminophen, their plasma elimination half-life may increase.

Stop use and ask a doctor if

- cough and pain gets worse or persist for more than a week and accompanied by rash, flare, itching, nausea, vomiting, edema (swelling), dysuria, or insomnia.
- fever gets worse or lasts more than 3 days.
- new symptoms occur.
- cough come back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

If pregnant, potentially-pregnant, or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Uses

Uses temporarily relieves common cold/flu symptoms:

- runny nose • sneezing • nasal congestion • sore throat • cough due to minor throat and bronchial irritation • fever • headache • minor pains and aches

Directions

Directions:

- take only as directed • do not exceed 8 doses per 24 hours

One dose 30 minutes after meals, three times a day
adults & children 12 yrs & over ----- 20 mL/dose
children under 12 yrs ----- do not use

OTHER INFORMATION

Other information

- each 20 ml contains: sodium 27 mg
- store between 20~25°C (68~77°F).
- protect from direct sunlight and keep in a low-humidity and cool place.
- do not store in a different container to prevent misuse and preserve quality.

QUESTIONS

Questions? 82-2-2204-7000 www.daewonpharm.com/en/

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 20mL Pouch



READ FULL PRODUCT LABELING BEFORE USE
[Active ingredients(in each 20 mL pouch) Purpose] Acetaminophen 300 mg Pain reliever/fever reducer Ephedrine HCl 18 mg Nasal decongestant Guaifenesin 42 mg Expectorant
[Directions] • take only as directed • do not exceed 8 doses per 24 hours One dose 30 minutes after meals, three times a day adults & children 12 yrs & over : 20 mL/dose children under 12 yrs : do not use
This Unit Not For Individual Sale



LOT No. :
EXP. DATE :

(01)08806718061119

Smart cut ↑

daewon
대원제약

자 먹는 기침감기약 Simply squeeze
콜대원
ColdaeWon

Multi Symptom Cough Relief
기침 / 인후통 / 가래
(Cough) (Sore throat) (Phlegm)
코프에이시럽
Cough A Syrup
0.68 FL OZ (20 mL)



[Other information] • each 20 ml contains: sodium 27 mg • store between 20~25°C (68~77°F). • protect from direct sunlight and keep in a low-humidity and cool place. • do not store in a different container to prevent misuse and preserve quality. [Questions?] 1-562-281-5888 Monday-Friday 9AM~6PM EST Distributed by : KP Global Inc. (Cerritos, CA 90703)

Manufactured by
daewon 대원제약
Made in Korea

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - Carton

Drug Facts

Active ingredients (in each 20 mL pouch) Purpose

Acetaminophen 300 mg Pain reliever/fever reducer
Ephedrine HCl 18 mg Nasal decongestant
Guaifenesin 42 mg Expectorant

Uses temporarily relieves common cold/flu symptoms: • runny nose • sneezing • nasal congestion • sore throat • cough due to minor throat and bronchial irritation • fever • headache • minor pains and aches

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take

• more than 8 doses in 24 hours, which is the maximum daily amount for this product • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product

Allergy Alert: If you have ever experienced allergic reactions induced by drugs. Symptoms may include: • Skin reddening • Blisters • Rash

If a skin reaction occurs, stop use and seek medical help right away.
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Reye's syndrome: a chickenpox or influenza-suspected infant or child under 15 years of age

If it is accompanied by nausea or vomit, it may be early symptoms of Reye's syndrome, rare but serious, consult a doctor promptly.

Do not use

• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. • if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug conditions an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

• liver disease • heart disease • renal disease • high blood pressure • thyroid disease • diabetes • glaucoma • dysuria • weak condition • high fever • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, pulmonary emphysema, and excessive sputum production • trouble urinating due to enlarged prostate gland • a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

• taking sedatives or tranquilizer • taking blood thinning drug warfarin

When using this product

• observe usage and dosage instructions. • do not take this drug for a long term. • children should take this drug under the guardians' supervision. • do not drink alcohol while you are taking this drug. • tends to cause drowsiness, avoid driving cars and operating machinery while taking this drug. • patients, administered with barbitol drugs, tricyclic antidepressants, or alcohol, tend to lack the ability to metabolize lots of acetaminophen, their plasma elimination half-life may increase.

Stop use and ask a doctor if

• cough and pain gets worse or persist for more than a week and accompanied by rash, flare, itching, nausea, vomiting, edema (swelling), dysuria, or insomnia. • fever gets worse or lasts more than 3 days. • new symptoms occur. • cough come back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

If pregnant, potentially-pregnant, or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

• take only as directed
• do not exceed 8 doses per 24 hours
One dose 30 minutes after meals, three times a day

adults & children 12 yrs & over	20 mL/dose
children under 12 yrs	do not use

Other information

• each 20 ml contains: sodium 27 mg
• store between 20-25°C (68-77°F).
• protect from direct sunlight and keep in a low-humidity and cool place.
• do not store in a different container to prevent misuse and preserve quality.

Inactive ingredients

xanthan gum, stevia 100s, acesulfame potassium, concentrated glycerin, sucralose, d-sorbitol solution, xylitol, sodium chloride, povidone K30, propylene glycol, ethanol, disodium edetate hydrate, citric acid, sodium citrate hydrate, sodium benzoate, lemon essence, apple mint flavor 514165, red no. 40, purified water

Questions? 1-562-281-5888

Monday-Friday 9AM-6PM EST
Distributed by : KP Global Inc.
(Cerritos, CA 90703)

LOT No. :

EXP. DATE :



8 806718 061126

Manufactured by

Daewon 대원제약

Head Office: 386, Cheonhodaero, Seongdong-gu, Seoul, Republic of Korea
Plant: 24, Jeyalgongdan 1-gil, Hyangnam-eup, Hwasong-si, Gyeonggi-do, Republic of Korea

짜 먹는 가침감기약
Simply squeeze

콜대원

ColdaeWon

코프에이시럽

Cough A Syrup

For adults

Smart cut

Multi Symptom
Cough Relief

짜 먹는 가침감기약
Simply squeeze

콜대원

ColdaeWon

코프에이시럽
Cough A Syrup



가침
(Cough)



인후통
(Sore throat)



가래
(Phlegm)

3.4 FL OZ (100 mL) / 5 Pouches
x 0.68 FL OZ (20 mL)

Daewon 대원제약
Made in Korea

Smart cut

Multi Symptom
Cough Relief

짜 먹는 가침감기약
Simply squeeze

콜대원

ColdaeWon

코프에이시럽
Cough A Syrup



가침
(Cough)



인후통
(Sore throat)



가래
(Phlegm)

3.4 FL OZ (100 mL) / 5 Pouches
x 0.68 FL OZ (20 mL)

Daewon 대원제약
Made in Korea

COLDAEWON COUGH A

acetaminophen, ephedrine hcl, guaifenesin syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72460-810
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	Acetaminophen	300 mg in 20 mL
Guaifenesin (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	Guaifenesin	42 mg in 20 mL
EPHEDRINE HYDROCHLORIDE (UNII: NLJ6390P1Z) (EPHEDRINE - UNII:GN83C131XS)	EPHEDRINE HYDROCHLORIDE	18 mg in 20 mL

Inactive Ingredients	
Ingredient Name	Strength
xanthan gum (UNII: TTV12P4NEE)	
glycerin (UNII: PDC6A3C0OX)	
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	APPLE, MINT, LEMON	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72460-810-01	5 in 1 CARTON	06/01/2019	
1		20 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/01/2019	

Labeler - Daewon Pharmaceutical Co., Ltd. (689275501)

Registrant - Daewon Pharmaceutical Co., Ltd. (689275501)

Establishment			
Name	Address	ID/FEI	Business Operations
Daewon Pharm. Co., Ltd. Hwaseong Factory		688235368	manufacture(72460-810)